Journal of Clinical & Analytical Medicine
Original Research

Microbiological assessment of intraocular lenses beyond their expiration dates

Microbiological contamination risk in expired intraocular lenses

Yüksel Totan[1], Mehmet Serdar Dervişoğulları[2], Hatice Uludağ Altun[3], Tuba Meral[3]
[1]Maya Eye Center Ankara,
[2]Department of Ophthalmology, Başkent University Adana Clinic and Research Center, Adana,
[3]Department of Medical Microbiology, Turgut Ozal University, Ankara, Turkey

Abstract

Aim: Ophthalmic surgeons prefer not to use expired intraocular lenses (IOL) in routine surgery mainly because of the feared risk of intraocular infection due to microbiologically contaminated IOL. In this pilot study, we aimed to evaluate the microbiological contamination of IOL in their packages with expired dates. Material and Method: This was a cross-over study in a university setting. Twenty-four IOL samples beyond their expiration dates, from four different manufacturers, were included in the current study. Swab samples were taken from the inner surface of the outer pouches and the surface of the outer box of the IOL. The IOL itself was inoculated directly to thioglycollate broth. The fluids containing the IOL were inoculated into BACTEC aerobic and anaerobic blood culture vials. All culture vials were sub-cultured and smears from all culture vials were stained by Gram's stain. Following the incubation period, during which growth was obtained on culture plates and blood culture vials, the colonies were identified by species based on colony morphology, Gram staining, and assimilation features using the BBL Crystal Gram-positive Identification Kit (Becton Dickinson, USA). Results: Staphylococcus epidermidis, capitis, and aureus were identified in the inner surface of the outer pouches of the packages in 4 IOL. Staphylococcus epidermidis was identified in the outer surface of the box of one IOL. Discussion: Only 4 of the 24 IOL packages beyond their expiration dates were contaminated microbiologically. There was no contamination on the IOLs devices themselves. The results suggest an unrealistic fear of ophthalmic surgeons for intraocular infection with the use of an expired IOL. Further studies including the chemical and physical stability, infrared and ultraviolet spectroscopy, nuclear magnetic resonance spectroscopy, refractive index, elemental analysis, surface microscopy, and biocompatibility may identify what changes might take place in expired IOL besides microbiological contamination.

Keywords

Contamination; Intraocular Lens; Cataract; Expiration Date; Microbiologic

DOI: 10.4328/JCAM.5851 Received: 02.04.2018 Accepted: 08.05.2018 Published Online: 14.05.2018 Printed: 01.03.2019 J Clin Anal Med 2019;10(2): 162-5
Corresponding Author: Mehmet Serdar Dervisogullari, Ophthalmology Department, Başkent University, Adana, Turkey.
T.: +90 322216767 F.: +90 31222635858 GSM: +905327720616 E-Mail: serdarderv@hotmail.com
ORCID ID: 0000-0003-2006-2906

Introduction

All invasive procedures involve contact by a medical device or a surgical instrument with a patient's sterile tissue or mucous membranes. A major risk of all such procedures is the introduction of pathogenic microbes leading to infection.

Failure to properly disinfect or sterilize equipment may lead to transmission via contaminated medical and surgical devices. While ethylene oxide (EO) may not be the least toxic sterilizing agent for the corneal endothelium[1], and is also thought to be a causative factor in toxic anterior segment syndrome (TASS)[2], it is still the most common sterilizing agent for medical devices that are sensitive to heat or gamma irradiation treatment.[3] Compared to other techniques, EO has some advantages (it penetrates medical packaging and many plastics, it is compatible with most medical materials, and has a cycle easy to control and monitor) and disadvantages (it has potential hazards to staff and patients, needs an aeration time, and is toxic, carcinogenic, and flammable).[4] Packs of sterile instruments or materials that are to be stored for more than a week are double wrapped in packaging that is impermeable to water. The date of sterilization is clearly marked on the outer wrapper. Expiration dates vary with packaging materials, but a general guideline is two months from the date of sterilization. Commercially available plastic dust covers will extend the shelf life to 6-12 months.[5] EO sterilization has an expiration date like every sterilization technique, but results from a university microbiology laboratory showed that the contents remained sterile for years after their expiration dates.[6]

Ophthalmic surgeons prefer not to use expired intraocular lenses (IOL) in routine surgery because of the risk of intraocular infection with the microbiologically contaminated IOL, yet there have been no reports in the literature to answer the question clearly: How realistic or scientific is this fear? Thus, we have conducted a pilot study to evaluate the microbiological contamination risk of the IOL and their packages beyond their expiration dates.

Material and Method

The study was performed in adherence with the tenets of the Declaration of Helsinki and was approved by the Turgut Özal University local ethics committee. Twenty-four expired IOL samples, from four different manufacturers, were included in the current study. Of the 24 kits, 19 were in dry medium, while 5 were in liquid medium. The length of time passed after the expiration dates of the IOL are shown in Table 1. Sampling and sample transfer process on the culture media were performed using aseptic technique under operating room conditions.[7]

Swab samples were taken from the inner surface of the outer pouches and the surface of the outer box of the lens, and the lenses were inoculated directly to thioglycollate broth (Figure). The swab samples were taken using sterile swab tubes (Copan, Italy) moistened with 1 ml of sterile 0.9% NaCl. The directly inoculated thioglycollate broths were transported to the microbiology laboratory using the required process, and the broths were incubated at 37°C for 7 days. Following the incubation period, without regard to blurring, all broths were cultivated on chocolate agar (Oxoid Australia, Sydney), 5% sheep blood agar, and Eosin Methylene Blue (EMB) agar (Salubris, Turkey); smears

Table 1. Brand marks and production dates.

Trademark	Lot no	Expiration Date
Abbott Medical Optics TECNIS1	4052960806	2010-6
	4009110805	2010-5
	4230280808	2010-8
	5210530805	2010-5
	5814311104	2014-04
Dr. Schmidt Micrpolex	590755-165	2010-03
	411226-462	2011-5
	463456-119	2011-12
	332357-132	2012-08
	572868-147	2013-10
Acriva BB UD613	A13230A000875	2011-09
	A13225A0000833	2011-07
	A01370A0000039	2010-05
	A13215A0000213	2011-07
	A13225A0000815	2011-07
ALCON AcrySof IQ	10604748008	2011-12
	20908935068	2014-5
	20907967044	2014-04
	20907967057	2014-04
	20708427081	2012-09

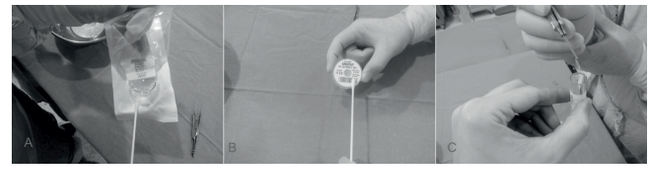

Figure. Swab samples were taken from the inner surface of the outer pouch (A) and the surface of the outer box located on the lens (B), and the lens itself was inoculated directly to thioglycollate broth (C).

Table 2. Colonizing agents

Trademark	The paper part of the inner surface of the outer pouch		The outer surface of the lens box		Lens	
	Growth	No growth	Growth	No growth	Growth	No growth
Abbott Medical Optics TECNIS1		+		+		+
	S. epidermidis		S. epidermidis			+
	S. epidermidis S. capitis		S. epidermidis			+
	S. epidermidis			+		+
	S. aureus			+		+
Dr. Scmidt Micrpolex		+		+		+
		+		+		+
		+		+		+
		+		+		+
		+		+		+
Acriva BB UD613		+		+		+
		+		+		+
		+		+		+
		+		+		+
		+		+		+
ALCON AcrySof IQ		+		+		+
		+		+		+
		+		+		+
		+		+		+
		+		+		+

from the liquid media were stained by Gram's stain (2).[8] The culture media were assessed for growth daily for seven days.

The same sampling procedures were performed for the lenses in the liquid medium as for the dry lenses. The fluids in the lens were inoculated into BACTEC aerobic and anaerobic blood culture vials. After inoculation the culture vials were loaded into a BACTEC 9120 (BD Diagnostic Systems, Sparks, MD) instrument. All the study culture vials were incubated for seven days.[9, 10] After seven days of incubation, regardless of positive alarms, all culture vials were sub-cultured on chocolate agar, 5% sheep blood agar, and EMB agar. Smears from all culture vials were stained by Gram's stain. After confirming that there was no growth on plates, these results were considered negative.

Following the incubation period during which growth was obtained on culture plates and blood culture vials, the colonies were identified by species based on colony morphology, Gram staining, and assimilation features using the BBL Crystal Gram-positive Identification Kit (Becton Dickinson, USA).

Results

Microbiological contamination at the inner surface of the outer pouches (Figure-A) was identified in 4 of 24 IOL. But only 2 of the IOL box outer surfaces (Figure-B) were found to be contaminated microbiologically. There was no contamination on any IOL itself (Figure-C). Common microbiological colonizing agents of the samples taken from the outer pouches and the surface of the outer box of the IOL are shown in Table 1.

Discussion

Ophthalmic surgeons prefer not to use expired IOL in routine surgery because of their fear of intraocular infection risk due to microbiologically contaminated IOL. In addition, there may be changes in the mechanical and optical properties of an expired IOL. To the best of our knowledge, this is the first study to assess the microbiological contamination of IOL beyond their expiration dates. Although there are not enough reports in the literature about expired IOL, starting from the microbiological analysis of the expired IOL, further studies may help answer this question: Can these expired IOL be used after re-sterilization? If we can find an answer, lowering the costs of cataract surgery with re-sterilization of expired IOLs may ease the Vision 2020 goals of WHO[11], especially in developing and underdeveloped countries.

The majority of bacteria causing endophthalmitis after cataract surgery in Western countries are Gram-positive microbes, observed with varying frequency in reported series. Bacteria most commonly identified in endophthalmitis after cataract surgery in many Western countries may include coagulase-negative staphylococci (Staphylococcus epidermidis), Staphylococcus aureus (including methicillin-resistant S. aureus), β-hemolytic streptococci, and Enterococcus faecalis among Gram-positive organisms; Gram-negative rods, including Haemophilus influenzae; and Pseudomonas aeruginosa among Gram-negative microorganisms.[12] In our study, microbiological agents seen in IOL with expired dates were Staphylococcus epidermidis, capitis, and aureus. It seems that Staphylococcus ssp. are the major microbiological group to contaminate expired IOL; they also play an important role in the contamination of other surgical instruments and in causing endophthalmitis.[13]

The expiration date of sterilization is directly related to the packaging. In our study, microbiological contamination at the inner surfaces of the outer pouches was identified in 3 of 24 IOL. But only 2 of the lens box outer surfaces were found to be contaminated microbiologically and this is possibly related to the inner pouches of the packages. There was no contamination on any IOL. Double wrappers seem to decrease the passage of microbiological agents to the IOL.

For effective sterilization, selection of packaging material plays an important role apart from sterilization parameters. The packaging material must be permeable enough for ethylene oxide and moisture to enter the package and also for air escape but must be impermeable to bacteria and other contaminants. The packaging material must not be deformed or its porosity altered by pressure variations during vacuum cycles. All plastic films used for wrapping should be evaluated on their ability to allow reasonable permeation of EO gas, moisture, and air before and after sterilization. Permeability is one of the most important criteria. Not only must the sterilizing agent be able to permeate the package, but the packaging material must also have sufficient breathability to permit release of toxic residues (e.g. ethylene oxide residual gas). Additionally, the porosity and bond strength (the seal, or bond, between two packaging substrates) must be sufficient to maintain package integrity. For proper and safe EO sterilization of medical devices, packaging materials and sterilization parameters go together. They need careful monitoring and selection.[14]

There are many other factors important in the storage stability of an IOL besides microbiological contamination. According to the FDA, the storage stability of the IOL is important and stability tests made at regular intervals should include the parameters of permeability, chemical and physical stability, light transmittance, extractables, physical property profile, average molecular weight, molecular weight, infrared and ultraviolet spectroscopy, nuclear magnetic resonance spectroscopy, melting point, solubility in water, refractive index, elemental analysis, surface microscopy, biocompatibility, and heat deformation temperature. Special importance should be given to monitoring change in mechanical and optical properties, because aging may be used as supporting evidence of stability. Stability results obtained at the storage temperature (the room temperature for the packaged IOL) of the device is the basis for the establishment of an expiration date.[15]

So what are the benefits of re-sterilization? According to the World Health Organization (WHO), 285 million people are estimated to be visually impaired worldwide: 39 million are blind and 246 million have low vision. Globally, uncorrected refractive errors are the main cause of moderate and severe visual impairment. Cataracts remain the leading cause of blindness in middle- and low-income countries and about 90% of the world' s visually impaired live in low-income settings. The number of people visually impaired from infectious diseases has been reduced in the last 20 years according to global estimates, but cataract rates remain the same and cataracts remain one of the preventable or curable causes of 80% of all visual impairment.[16] We must note that manual small incision cataract surgery (SICS) is the most cost-effective and suggested technique to prevent cataract-associated blindness in developing coun-

tries and IOL are the most costly component.[17] Lowering the costs may also help to reach VISION2020 goals.[17]

The major limitation of our study was that we only assessed the microbiological contamination. Optical and mechanical properties should also be studied. Electron microscopy and spectroscopy should be added to show the infrastructural changes in the expired IOL. Another limitation was the assessment of contamination only in laboratory conditions. Animal experiments with the implantation of the expired IOL should be investigated further.

In conclusion, only 4 of the 24 IOL packages beyond their expiration dates were contaminated microbiologically. Further studies including the chemical and physical stability, infrared and ultraviolet spectroscopy, nuclear magnetic resonance spectroscopy, refractive index, elemental analysis, surface microscopy, and biocompatibility may identify what changes might take place in expired IOL besides microbiological contamination. Furthermore, these studies may also include all ophthalmic devices other than IOL.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

Funding: None

Conflict of interest

None of the authors received any type of financial support that could be considered potential conflict of interest regarding the manuscript or its submission.

References

1.Singh G, Böhnke M, von Domarus D, Draeger J. Toxicity of methods of implant material sterilization on corneal endothelium. Ann Ophthalmol. 1985; 17(11):727-30.

2. Ari S, Caca I, Sahin A, Cingü AK. Toxic anterior segment syndrome subsequent to pediatric cataract surgery. Cutan Ocul Toxicol. 2012; 31(1):53-7.

3. Mendes GC, Brandão TR, Silva CL. Ethylene oxide sterilization of medical devices: a review. Am J Infect Control. 2007; 35(9):574-81.

4. William A, Rutala PhD, David J, Weber MD. Disinfection and sterilization: An overview. American Journal of Infection Control 2013; 41 : S2-S5.

5. Nakamura K, Kiminami H, Yamashita A, Abe Y, Yoshino K, Suzuki S. Assessment of the effects of sterilization methods on protein drug stability by elucidating decomposition mechanism and material analysis. Int J Pharm. 2015; 484(1-2):51-6.

6. Worthington P. Sterility of packaged implant components. Int J Oral Maxillofac Implants. 2005; 20(3):461.

7. WHO Blood Safety and Clinical Technology. Guidelines on Standard Operating Procedures for Microbiology. Chapter 6 - Cultivation of Bacteria on Laboratory Media, Aseptic techniques. 2000.

8. Murray PR, Baron EJ, Jorgensen JH, Landry ML, Pfaller MA. Manual of Clinical Microbiology, 9th ed. Clinical Microbiology, Translation ed, Basustaoglu A. Atlas Press, Ankara, 2009.

9. Pal N, Sharma R, Rishi S, Vyas L. Optimum Time to Detection of Bacteria and Yeast Species with BACTEC 9120 Culture System from Blood and Sterile Body Fluids. J Lab Physicians. 2009; 1(2):69-72.

10. Balıkcı A, Belas Z, Eren Topkaya A. Blood culture positivity: is it pathogen or contaminant? Mikrobiyol Bul. 2013; 47(1):135-40.

11. Lewallen S, Lansingh V, Thulasiraj RD. Vision 2020: moving beyond blindness. . Int Health. 2014; 6(3):158-9.

12.ESCRS guidelines on prevention and treatment of endophthalmitis following cataract surgery. The European Society for Cataract and Refractive Surgeons; 2013.

13. Linertová R, Abreu-González R, García-Pérez L, Alonso-Plasencia M, Cordovés-Dorta LM, Abreu-Reyes JA, et..Intracameral cefuroxime and moxifloxacin used as endophthalmitis prophylaxis after cataract surgery: systematic review of effectiveness and cost effectiveness.Clin Ophthalmol. 2014 :14(8):1515-22.

14.MortonPJ, Conner R. Implementing AORN recommended practices for selection and use of packaging systems for sterilization. AORN J. 2014; 99(4): 495-502

15.Geoffrey S. Clark. SHELF LIFE OF MEDICAL DEVICES. Implementation of FDA's Good Guidance Practices. 1997.

16. World Health Organisation (WHO) Media Centre. Visual impairment and blindness. Fact Sheet N°282 Updated. 2014

17. Khanna R, Pujari S, Sangwan V. Cataract surgery in developing countries. Curr Opin Ophthalmol. 2011; 22(1):10-4.

How to cite this article:

Totan Y, Dervişoğulları MS, Altun HU, Meral T. Microbiological assessment of intraocular lenses beyond their expiration dates. J Clin Anal Med 2019;10(2): 162-5.